UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 27 1989

MEMORANDUM

SUBJECT: PP #8F3663. (RCB # 5056) DPX-M6316 (Pinnacle™) on Soybeans. Amendment of 2/28/89. MRID Nos. 410152-01, 410152-02

FROM: Cynthia Deyrup, Ph.D., Chemist C Deyrup
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Acting Chief
Dietary Exposure Branch
Health Effects Division (H7509C) Richard D Schmitt

TO: Robert Taylor, Product Manager No. 15
Registration Division (H7505C)

and

Toxicology Branch-Herbicide, Fungicide and Anti-Microbial Support
Hazard Evaluation Division (H7509C)

Background

E.I. du Pont de Nemours and Company (Inc.) had proposed a tolerance of 0.10 ppm on soybeans for residues of Pinnacle™ or DPX-M6316 [methyl 3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] amino]-sulfonyl]-2-thiophenecarboxylate].

The present amendment addresses the deficiencies cited in DEB's review of 9/8/88 (memo of C. Deyrup).

The numbering of the deficiencies follows that used in the 9/8/88 review.

Summary of Remaining Deficiencies

All outstanding deficiencies have been resolved.

Recommendations

TOX and EAB considerations permitting, DEB recommends that the proposed tolerance of 0.10 ppm for residues of thifensulfuron-methyl (DPX-M6316) on soybeans be established.

Deficiency 1a

The product chemistry of DPX-M6316 was discussed in DEB's memos of 2/12/87, 12/24/87, 4/1/88, and 5/3/88 in conjunction with PP #6F3431 (memos of C. Deyrup).

DEB concluded that the petitioner would need to submit analyses determining the levels of the impurities designated Y and Z in the technical, once commercial production has begun. In its 12/24/87 review, DEB also stated that if the submitted analyses of technical DPX-M6316 were of material produced with Semiworks equipment, analyses of batches of technical material would also be needed after commercial production had begun.

Therefore, analyses of DPX-M6316, reflecting determinations of the impurities Y and Z, are now required, if DPX-M6316 is in commercial production.

Petitioner's Response to Deficiency 1a

The petitioner has identified impurities Y and Z and has submitted analyses of 6 batches of technical DPX-M6316. The details of this response are given in the Confidential Appendix to this review.

DEB's Comments/Conclusions, re: Deficiency 1a

Deficiency 1a is resolved. DEB anticipates no residue problems from Impurities Y and Z.

Deficiencies 4, 6a, and 6b

These deficiencies all involved DEB's inability to validate the method used to generate the residue data, because standard curves had not been submitted.

Petitioner's Response to Deficiencies 4, 6a, and 6b

The petitioner has submitted a supplement to the analytical methodology (No. AMR-973-87). The supplement contains a standard curve for DPX-M6316 and the chromatograms which were used to generate the standard curve.

DEB's Comments/Conclusions, re: Deficiencies 4, 6a, and 6b

DEB concludes that the method used to generate the residue data is adequate. The residue data adequately support the proposed tolerance of 0.10 ppm on soybeans. The residue data also demonstrate that residues of DPX-M6316 do not concentrate in soybean oil.

Deficiencies 4, 6a, and 6b are resolved.

Attachment 1: International Residue Limit Status Sheet
Attachment 2: Confidential Appendix

cc with Attachments 1 and 2: PMSD/ISB, Reviewer-Deyrup, PP#8F3663
RF, TOX-HFAS, PM #15
cc with Attachment 1 only: Circu, SF, SACB/TAS-Tomerlin
RDI:J. Onley:3/24/89:R. A. Loranger:3/24/89
TS-769:CM#2:RM810:X7484:C. Deyrup:cd:3/27/89

Pages 4-5 – *Manufacturing process information may be entitled to confidential treatment*

Attachment 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Sulfothifenuron DPX-M6316

CODEX NO. _____

CODEX STATUS:

☒ No Codex Proposal Step 6 or above

Residue(if Step 8): _____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 8F 3663

RCB Reviewer Deyrup

Residue: Me-3-[[[[(4-Methoxy-6-Me 1,3,5-triazin-2-yl)amino]carbonyl amino]sulfonyl]2-thiophene carboxylate

Crop(s)	Limit (mg/kg)
Soybeans	0.1 ppm

CANADIAN LIMITS:

☒ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)